

**ATTORNEY DOCKET NO.: RSW 85162 US
Application Serial No. 10/527,921
PATENT**

REMARKS

In the Office Action, claim 4-29 were noted as having improper multiple dependency. Claims 2-21 were withdrawn from consideration as nonelected, as was claim 24. Claims 25-29 were noted to be improper multiply dependent claims. Claims 1, 22, 23 and 25-29 were rejected under 35 USC 112, second paragraph as allegedly indefinite. Claims 1 and 22 were rejected under 35 USC 102(b) as allegedly anticipated by Masuhara et al. (US 2001/0002994, "Masuhara"). Claim 23 was rejected under 35 USC 103(a) as allegedly obvious over Masuhara in view of Pratt (US 4,849,223, "Pratt").

The claims have been amended to remove improper multiple dependencies and for clarity. Support may be found throughout the application and claims as filed. No new matter is added. New claim 30 is based on original claim 1.

Information Disclosure Statement

The Information Disclosure Statement of March 16, 2005 ("IDS") was not considered for allegedly failing to include copies of each foreign patent document cited. This is believed to be an oversight, as the PAIR system indicates copies of each cited foreign patent are present on the PTO's electronic file wrapper (see various "Foreign Reference" files dated March 16, 2005, as filed with the application).

Consideration of the IDS of March 16, 2005 is respectfully requested.

The Rejection Under 35 USC 112, Second Paragraph

Claims 1, 22, 23 and 25-29 were rejected under 35 USC 112, second paragraph as allegedly indefinite on various grounds. This rejection is traversed and otherwise addressed below.

Claim 1 was rejection on the basis of the term "optionally" and "and/or" as allegedly rendering the claim indefinite. Claim 1 has been revised for clarity, and recites that the preparation formed in step a) comprises an organic solvent, an organometallic titanium oxide precursor and metal ions homogeneously dispersed in the preparation. The claim has also been

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revised to clarify that the metal ions can be in the form of metal salts and/or organometallic compounds. It is asserted that the term “and/or” is definite in meaning in the revised claim.

The remaining claims were apparently rejected as indefinite for their dependency on claim 1. As claim 1 has been amended, these rejections are similarly overcome.

Withdrawal of the rejection under 35 USC 112, second paragraph is respectfully requested.

The Rejection Under 35 USC 102(b)

Claims 1 and 22 were rejected under 35 USC 102(b) as allegedly anticipated by Masuhara et al. (US 2001/0002994, “Masuhara”). This rejection is traversed.

Masuhara describes the use of titanium oxides in dental and orological compositions. The Office Action asserted that Masuhara “discloses titanium oxide coating on an implant prepared by adding a preparation containing an organic solvent and an organometallic titanium oxide precursor, and applying the preparation prepared onto an implant, and drying the coating” Office Action, page 5.

Masuhara does not teach or suggest the use of a preparation comprising an organic solvent, an organometallic titanium oxide precursor, and metal ions homogeneously dispersed in the preparation. As described in the present application, prior art titanium oxide coatings did not comprise homogeneous metal ions, but rather utilized admixed powders or salt-like compounds of micrometer dimensions (see paragraph 0008 and 0009). This is consistent with Masuhara’s description of the optional use of fine metal or metal salt particles, and of silver particles having a mean diameter of 2 micrometers (see paragraph 136 and example 5). Masuhara thus does not teach or suggest the homogeneous dispersion of metal ions in a preparation.

As Masuhara fails to teach or suggest all the claim elements, Masuhara cannot anticipate the claimed invention. Withdrawal of the rejection under 35 USC 102(b) is respectfully requested.

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The Rejection Under 35 USC 103

Claim 23 was rejected under 35 USC 103(a) as allegedly obvious over Masuhara in view of Pratt (US 4,849,223, “Pratt”). This rejection is traversed.

As detailed above, Masuhara does not teach the homogeneous distribution of metal ions in a titanium oxide coating on an implant. Pratt fails to remedy this key deficiency.

Pratt simply describes the use of metallic silver coatings on titanium or tantalum oxide particles which are mixed in bone cements or deposited on catheters. Pratt does not teach or suggest any method of homogeneously distributing metal ions in a preparation, as the metal in Pratt is provided on coated particles: Pratt utilizes a “slurry” of TiO₂ in his working example, demonstrating that his preparation is not homogeneous. See column 6.

Furthermore, Pratt does not teach or suggest the use of organometallic titanium oxide precursors, which in the organic solvent preparation described here would not take the particle form used by Pratt. Pratt and Masuhara are thus not combinable, as they utilize fundamentally different forms of titanium having different properties, with Pratt utilizing or reciting a number of other non-titanium oxides.

The Office Action conclusorily states that it “would have been obvious to one of ordinary skill in the art to include an organometallic compound that disperses metal ions homogeneously in the preparation in order to provide a sustained antibacterial effect.” Office Action, page 6. None of the cited art, however, teaches or suggests the need for altering their methods to achieve a sustained antibacterial effect. Pratt, in fact, teaches that his invention already provides a sustained antibacterial effect (see col. 2, lines 37-41; claim 10; and elsewhere). Masuhara teaches that his compositions are effective over periods of months (see examples), and that the antibacterial effect can easily be restored by light exposure (see paragraph 146). The cited art thus teaches that it already provides sustained antibacterial effects, providing no motivation for modifying their teachings.

Furthermore, none of the cited art teaches or suggests that organometallic compounds can allow for dispersion of metal ions homogeneously, or can allow for a sustained antibacterial effect. In fact, this would be contrary to embodiments of the invention, which provide for the regulatable dissolution of metal ions from the surface of an implant, so as to allow an initial

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antibacterial phase uniformly over the surface of the implant resulting from the uniform distribution of metal ions, which ions are subsequently released from the surface and then allow the implant to enter a more biocompatible phase having lower metal release.

As none of the cited art teaches or suggests a method for obtaining the homogeneous distribution of metal ions within a titanium oxide coating on an implant, all of the claim elements are not provided by the cited art. Obviousness has thus not been established. Withdrawal of the rejection under 35 USC 103(b) is respectfully requested.

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CONCLUSION

CONDITIONAL REQUEST FOR TELEPHONIC INTERVIEW

Applicants respectfully submit that the claims are in condition for allowance. Should any issues remain after consideration of the above, the Examiner is requested to contact the undersigned at 858-228-7829 prior to the issuance of a subsequent action.

Respectfully submitted,

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